UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,448	09/29/2005	Jacek Rozga	3154/106	6295

2161 7590 09/08/2008

BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,448	ROZGA, JACEK	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the spinning loop separator as set forth in claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0033370 A1 to Bainbridge et al.

In the specification and figures, Bainbridge discloses the method substantially as claimed by Applicant.

With regard to claims 1-8, Bainbridge discloses a method of blood pheresis comprising the steps of a) attaching an extracorporeal circuit 10 to the bloodstream of a patient 4 (see FIG 1, paragraph 0086), b) removing blood from the patient 4 and conveying the blood to a filter 352 (see paragraphs 0086, 0087), c) filtering the blood with a spinning loop separator (centrifuge 568, processing vessel 352) that is capable of being adapted to remove a particular molecular weight substance at a first rate of about 20-140 mL/min for about 120-170 minutes (see paragraphs 0087, 0146, 0303), d) returning uncollected blood to the patient (see paragraph 0145), and e) infusing substitute fluid at a second rate that is appropriate for the patient (see paragraph 0146).

Bainbridge fails to specifically teach that the filter removes target molecules of the same weight claimed by Applicant. However, Applicant claims that the filter is "adapted to" or otherwise modified from the disclosed structure in order to perform the claimed operation. Furthermore, Bainbridge discloses that operations other than those

disclosed are contemplated within the scope of the invention (see paragraph 0309). It is the position of the Examiner that it is within the skill of a worker in the art to place the plasma removal passage of the blood processing vessel 352 at a level in the vessel 352 that is high enough to extract the lighter weight fractions that will be pushed to the top of the vessel 352 during centrifugation. Accordingly, the method disclosed by Bainbridge comprises a separator that may be adapted for removing the plasma fraction claimed by Applicant.

Bainbridge further fails to disclose the specific flow rate at which the selected plasma fraction is removed and substitute fluid returned to the patient. However, Bainbridge discloses that all pumping rates are variably controlled by pumps and controllers in order to maximize patient comfort and minimize processing time (see, for example, paragraph 0146). Accordingly, it is the position of the Examiner that, absent a showing of criticality or unexpected results with the use of the claimed pumping rates, adjustment of the pumping rates to ranges tolerated by the donor is within the skill of a worker in the art.

4. Claims 9, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0033370 A1 to Bainbridge et al in view of US 6,376,650 to Raa et al.

In the specification and figures, Bainbridge suggests the method substantially as claimed by Applicant with the exception of the composition of the plasma substitute. Raa discloses a plasma substitute that comprises peptide components in order to provide a suitable replacement plasma (see column 1, lines 25-35). With regard to the

specific molecular weight range claimed by Applicant, it is clear to one skilled in the art that a "substitute" fluid should mimic the fluid it is replacing as closely as possible. That is, if molecules of a particular molecular weight are being removed from a patient, a "substitute" fluid should comprise components in the same general weight range to substitute for the removed components. As such, it is the position of the Examiner that it would have been obvious to one having ordinary skill in the art at the time of invention to use a substitute solution of peptides, as disclosed by Raa, with appropriate molecular weights, in order to directly substitute for the removed plasma.

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0033370 A1 to Bainbridge et al in view of US 4,191,182 to Popovich.

In the specification and figures, Bainbridge suggests the method substantially as claimed by applicant with the exception of a membrane filter as a part of the spinning loop separator.

Popovich discloses a method of removing plasma fractions comprising the steps of attaching a treatment system to the patient comprising a filter 9, removing blood from the patient via line 1 and conveying it to the filter 9, filtering the blood to remove certain fractions from the blood, mixing the filtered fluid with a replacement fluid, and returning it to the patient (see column 6, lines 10-58). Popvich discloses that it is known in the art to use plasmapheresis processes to filter out particles as small as 10kDa, suggesting that the membrane filters have sizes that meet the size limitations claimed by applicant (see column 2, lines 1-5). All of the claimed elements are known in the art, and it is the

position of the Examiner that one having ordinary skill in the art at the time of invention would have been motivated to place a small pore filter as disclosed by Popovich at the exit of the processing vessel 352 of the spinning separator as disclosed by Bainbridge in order to separate out low-molecular weight components, as taught by Popovich.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,182 to Popovich in view of US 6,376,650 to Raa.

In the specification and figures, Popovich discloses the method substantially as claimed by Applicant. With regard to claim 20, Popovich discloses a method of removing plasma fractions comprising the steps of attaching a treatment system to the patient comprising a filter 9, removing blood from the patient via line 1 and conveying it to the filter 9, filtering the blood to remove certain fractions from the blood, mixing the filtered fluid with a replacement fluid, and returning it to the patient (see column 6, lines 10-58). Popvich discloses that it is known in the art to use plasmapheresis processes to filter out particles as small as 10kDa, suggesting that the membrane filters have sizes that meet the size limitations claimed by applicant (see column 2, lines 1-5).

Popovich fails to disclose that the replacement fluid comprises peptide components within a particular weight range. Raa discloses a plasma substitute that comprises peptide components in order to provide a suitable replacement plasma (see column 1, lines 25-35). With regard to the specific molecular weight range claimed by Applicant, it is clear to one skilled in the art that a "substitute" fluid should mimic the fluid it is replacing as closely as possible. That is, if molecules of a particular molecular

weight are being removed from a patient, a "substitute" fluid should comprise components in the same general weight range to substitute for the removed components. As such, it is the position of the Examiner that it would have been obvious to one having ordinary skill in the art at the time of invention to use a substitute solution of peptides, as disclosed by Raa, with appropriate molecular weights, in order to directly substitute for the removed plasma.

Response to Arguments

7. Applicant's amendment and remarks filed 11 June 2008 have been entered and fully considered.

8. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
4 September 2008